

II. REMARKS

A request for a two-month extension of time, up to and including June 4, 2008, along with the appropriate fee, accompany this Reply.

A. Status of the Claims

Claims 1-9 and 12-19 were pending for purposes of the instant Office Action. Claims 10-11 and 20-22 were previously withdrawn from consideration and Claims 3 and 14 are now canceled. Claims 23-42 were previously canceled. Accordingly, Claims 1-2, 4-9, and 12-13 and 15-19 remain pending.

Claims 1 and 4 are amended in this Reply. Support for the amendment to claim 1 can be found in the specification, e.g., at page 2, lines 8-9 (paragraph [0023] of the published version of the application) page 8, lines 22-24, and page 9, lines 15-16. Claim 4 is amended to change its dependency from canceled claim 3, to pending claim 1. It is respectfully submitted that no new matter was added by virtue of this amendment.

Reconsideration of the application is respectfully requested.

B. Claim Objections

Claims 3, 4, and 14 were rejected under 35 USC 112, second paragraph as being indefinite over the recitation of "particularly well adapted for amplification via PCR." Applicants respectfully disagree, but have canceled Claims 3 and 14 in order to expedite prosecution of this application toward

allowance. Claim 4 has been amended to depend from Claim 1, which does not include the offending language. Accordingly, applicants submit that the rejection based on indefiniteness of these claims is moot, and respectfully request reconsideration and withdrawal of the rejection to claims 3, 4, and 14 under 35 U.S.C. 112, second paragraph be withdrawn.

B. Claim Rejections under 35 USC §102

Claims 1-9 and 12 stand rejected under 35 USC 102(b) as being anticipated by Walker (EP 0585660). Applicants respectfully traverse in view of the current amendment to Claim 1 (and therefore Claims 2, 4-9 and 12 which depend from Claim 1).

Claims 1-2, 4-9 and 12 (claim 3 being canceled) now recite “[a] method of pretreating a nucleic acid sample ... to remove or inactivate contaminating nucleic acids purposefully introduced to a site or sample to confound future analysis of target nucleic acids present in the sample.” Walker fails to disclose removal of nucleic acids which are purposefully introduced into the sample as contaminants *prior to analysis of the sample*. Instead, Walker provides for a method to remove single stranded amplicon contamination from prepared nucleic samples. Amplicons are products of a nucleic acid amplification reaction, and are therefore introduced during analysis of the sample – not contaminants which are purposefully introduced to confound future analysis of the sample – and introduced prior to any analysis is conducted on the sample. Walker is therefore concerned only with laboratory-derived contamination.

In view of this distinction, Walker does not describe each and every element of the invention as claimed in Claims 1-2, 4-9 and 12, and thus cannot anticipate these claims under 35 USC 102.

Furthermore, the method of Walker, which describes a means to determine whether a result was genuine or a false positive caused by contamination occurring *during* analysis in the laboratory would be unable to determine the presence of contamination in samples contaminated *prior to their analysis* in the laboratory. There is not teaching or suggestion in Walker that the method can be used or modified in some way to be used for removing contaminants introduced prior to analysis of the sample in accordance with the subject invention. Accordingly, it is submitted that the claimed invention is novel, and would also have been unobvious in view of the teaching of Walker.

Withdrawal is respectfully requested of the rejection under 35 U.S.C. §102(b), citing Walker, of independent claim 1, and its dependent claims 2, 4-9 and 12.

Rejection under 35 USC 102(b) - Miwa (U.S. Patent 4,514,502)

Claims 1-3, 5, 6, 8, 9 and 12 to 19 were rejected under 35 USC 102(b) as being anticipated by Miwa (U.S. Patent 4,514,502).

Miwa describes a method for employing RNase I to treat a sample of laboratory-prepared plasmid DNA and removing any contaminating RNA which remains from an earlier bacterial lysis step. See Miwa, col.6, lines 56 - 68 through col. 7, lines 1 - 6 and 48 - 51. Therefore, Miwa, like Walker, is concerned only with *laboratory-derived contamination* of nucleic acid samples – contamination resulting *during analysis*, from the laboratory testing procedures themselves.

Miwa does NOT describe removal of contamination that has been purposefully introduced to – *prior to analysis of* – the sample, where the contaminant is introduced to confound its analysis, as currently claimed. As discussed for the Walker reference, above, Miwa therefore does not anticipate claim 1 which now expressly recites removal of contaminants “purposefully introduced to a [sample]

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to confound future analysis of ... the sample." See claim 1. Although Miwa describes contamination that occurs during the analysis that may confound the future analysis of the sample, that contamination is still introduced *during* the laboratory analysis. The claimed invention requires that the contaminant is introduced *prior to* the analysis. Nor is there any teaching or suggestion in Miwa that such method as now claimed can be carried out by modifying the process described in Miwa. Therefore, applicants maintain that the subject invention is novel, and would also have been unobvious in view of the description in Miwa.

Withdrawal of the rejection of claims 1-3, 5, 6, 8, 9 and 12-19, under 35 U.S.C. §102(b), citing Miwa, is respectfully requested.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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